



Medtronic

Cardioblate[®] 60889

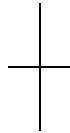
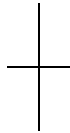
Diagnostic Kit

Directions for Use

Cardioblate_FC.fm 5/10/06 11:35 am

4.0 in x 6.5 in (101.6 mm x 165.1 mm)

Medtronic Confidential
CS005



M924669A001Rev A

Explanation of Symbols

	Attention, See Instructions for Use
	Nonsterile
	Lot Number
	Catalog Number
	Date of Manufacture
	Content
	Temperature Limitations
	Do not dispose of this product in the unsorted municipal waste stream.
	Monopolar
	Bipolar
	Overall RF Energy Delivery Time
	Volume Level
	Impedance
	Wattage
	Ohms, Unit of Impedance Measurement
	RF Energy Delivery Button
	Active Ablation Time
	Error Message Explanation

4.0 in x 6.5 in (101.6 mm x 165.1 mm)

W	Watts, Unit of Energy Management
↕	Maximum Limit
↕	Minimum Limit
	Test Information

Directions for Use
Cardioblate® Diagnostic Kit

Model
60889

Description

The Medtronic® Cardioblate® Diagnostic Kit is designed to allow the user to verify the operation of the Medtronic® Cardioblate® 68000 Generator. The Diagnostic Kit consists of two components: a Diagnostic Cable and a USB Flash Drive preloaded with the Diagnostic Application. The Cardioblate® Diagnostic Cable (Figure 1) is a nonsterile, reusable tool compatible with standard test equipment. The USB Flash Drive (Figure 2) comes preloaded with the Diagnostic Application used to test the generator independent from standard operating software used in a clinical environment.

Note: The Diagnostic Kit is to be used only in a non-sterile environment.

Note: The Diagnostic Cable and the Diagnostic Application are required to complete all necessary testing.

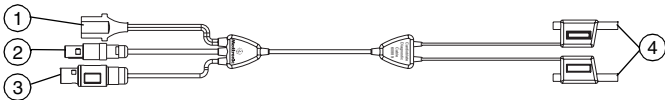


Figure 1. Diagnostic Cable

- 1. Dispersive Cable Connector
- 2. Monopolar Connector
- 3. Bipolar Connector
- 4. Banana-style stackable connectors



Figure 2. USB Flash Drive

Device Specifications

Default Settings

RF power	Monopolar mode: 20 W	
	Bipolar mode: NA	
Impedance (Monopolar Mode)	Maximum: 500 Ω	Minimum: 12 Ω
Impedance (Bipolar Mode)	Maximum: 500 Ω	Minimum: 12 Ω
RF timer	Monopolar mode: 2 minutes	

Temperature Information

Storage/shipping temperature and humidity	-40 to 66°C, 95% relative humidity
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Cleaning:

Wipe the Diagnostic Cable with a damp cloth as needed.

Warnings and Precautions

- Use extreme caution when working around test leads and loads while radio frequency (RF) energy is being applied.
- Do not touch any exposed leads.
- Use insulated leads if possible.
- The risk of shock or tissue ablation exists with these nonclinical setups.
- Power resistors may build up significant heat during use.

Note: Additional lead lengths may affect impedance readings.

Note: Due to the lead lengths required for this testing and the high frequency of the Cardioblate® 68000 Generator signal, it is normal for the generator-displayed value of impedance to vary from the actual value of the load resistor in the circuit.

Typically, a 300 Ω load appears to the generator as a load in the area of 285-325 Ω , and a 100 Ω load appears as a load in the area of 100-110 Ω , which is normal.

Equipment

In addition to the Cardioblate® Diagnostic Kit, Model 60889, the following instruments are required to perform the tests:

- Cardioblate® 68000 Generator
- Digital Multimeter (DMM) – Agilent 34401A or equivalent (must be capable of AC measurements of 500 kHz, 180 Vrms)
- 50 Ω non-inductive load resistor (eg, Vishay Dale NH10050R00F 100W 1%)
- 100 Ω non-inductive load resistor (eg, Vishay Dale NH100100R0F 100W 1%)
- 300 Ω non-inductive load resistor (eg, Vishay Dale NH100300R0F 100W 1%)
- Test leads

Directions for Use

1. Prior to use, inspect the Diagnostic Cable and verify no cracks exist in any connector. Replace the Diagnostic Kit if damage has occurred.
2. Insert the USB Flash Drive into the side of the generator (Figure 3). The USB port is located on the lefthand side of the Cardioblate® 68000 Generator touchscreen.

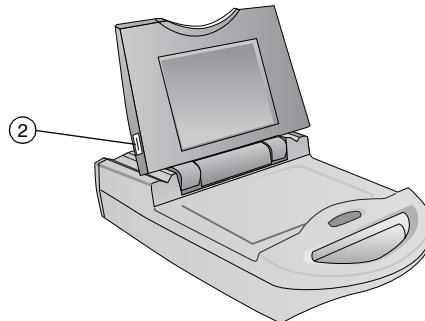


Figure 3. Insert USB Flash Drive

3. Turn on the generator via the power switch located on the rear of the generator. Once the generator completes its self-test, the Service Menu screen will appear (Figure 4).

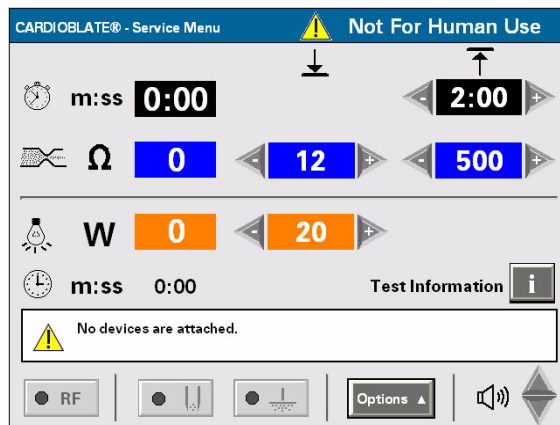


Figure 4. Service Menu screen

4. Plug the monopolar, bipolar, and dispersive cable connectors into the therapy panel located on the right side of the generator. Verify the connections are fully inserted and seated. The screen should now appear as in Figure 5.

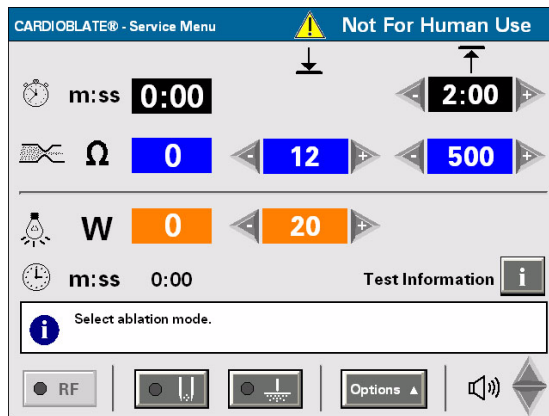


Figure 5. Service Menu, Devices Attached

Testing

1. Press the Test Information button  from the Service Menu (Figure 6) to enter Test Mode.

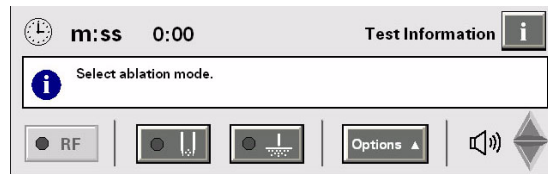


Figure 6.

2. Information on how to perform each test is listed below – this information is also available within the Diagnostic Application in the Test Information screen (Figure 7).

Note: In order to complete all necessary checks, tests must be performed in both bipolar and monopolar modes.

Test List		
Done ?	Test to Perform	Details
☐	RF Power Output	
☐	Bipolar Operation	
☐	Impedance Safety	
☐	Impedance Limits	
☐	Timing Control	
		

Figure 7. Test Information Screen

RF Output Power

1. Connect the Diagnostic Cable to the generator upon completion of self-test.
2. Connect test leads from the Diagnostic Cable to a 100 Ω load.
3. Connect the leads of the DMM across the 100 Ω load resistor (polarity does not matter).
4. Set the DMM to measure AC volts.
5. Set the RF timer to 2:00 minutes.
6. Select Monopolar mode on the generator.

6 English Directions for Use

7. Set the power output of the generator to 4 W.
8. Initiate an RF cycle.
9. Measure and record the DMM AC Vrms reading. The reading should be within 20 volts AC $\pm 10\%$.
10. Stop the RF cycle.
11. Repeat steps 8 through 10 for each of these power settings: 9 W (30 volts), 16 W (40 volts), 25 W (50 volts), 36 W (60 volts), and 49 W (70 volts).
12. Select Bipolar mode on the generator and ensure that the Power Mode box on the right side of the display is selected.
13. Repeat steps 7-11 and verify bipolar operation for various output power levels.

Bipolar Operation

1. Connect the Diagnostic Cable to the generator upon completion of self-test.
2. Connect test leads from the RF test cable to a 100 Ω load.
3. Connect the leads of the DMM across the 100 Ω load resistor (polarity does not matter).
4. Select Bipolar mode on the generator.
5. Ensure that the Power Mode box is NOT selected.
6. Initiate an RF cycle.
7. Verify power steps in 5 W increments.
8. Verify transmurality is reached.

Low-impedance safety check

1. Ensure that the Diagnostic Cable is connected to the generator.
2. Ensure there is a low-impedance circuit by disconnecting the test leads and shorting together.
3. Ensure that the RF timer is set to anything greater than 0:02 seconds.
4. Set the power output of the generator to 5 W.
5. Initiate an RF cycle.
6. The generator will immediately terminate RF delivery and display an error message describing a low-impedance condition.

High-impedance safety check

1. Ensure that the Diagnostic Cable is connected to the generator.
2. Ensure there is an open circuit by disconnecting at least one test lead from the Diagnostic Cable.
3. Ensure that the RF Timer is set to anything greater than 0:02 seconds.
4. Set the power output of the generator to 5 W.
5. Initiate an RF cycle.
6. The generator will immediately terminate RF delivery and display an error message describing a high-impedance condition.
7. Reset the high-impedance limit to 500 Ω .

Low-impedance limit check

1. Ensure that the Diagnostic Cable is connected to the generator.
2. Ensure the RF timer is set to 2:00 minutes.
3. Select Monopolar mode on the generator.
4. Set the power output of the generator to 5 W.
5. Connect test leads of the RF test cable to a load less than 100 Ω .
6. Set the low-impedance limit to a value higher than the load connected.
7. Initiate an RF cycle.
8. The generator will immediately terminate RF delivery and display an error message describing a low-impedance condition.
9. Reset the low-impedance limit to 12 Ω .

High-impedance limit check

1. Ensure that the Diagnostic Cable is connected to the generator.
2. Ensure the RF timer is set to 2:00 minutes.
3. Select Monopolar mode on the generator.
4. Set the power output of the generator to 5 W.
5. Connect test leads of the RF test cable to a load higher than 110 Ω .
6. Set the high-impedance limit to a value lower than the load connected.
7. Initiate an RF cycle.
8. The generator will immediately terminate RF delivery and display an error message describing a high-impedance condition.
9. Reset the high-impedance limit to 500 Ω .

RF Timer Test

1. Ensure that the Diagnostic Cable is connected to the generator.
2. Ensure that the RF timer is set to 1:00 minute.
3. Set the power output of the generator to 5 W.
4. Connect test leads from the RF test cable to a 100 Ω load.
5. Select Monopolar mode on the generator.
6. Initiate an RF cycle.
7. Ensure that RF delivery ceases when the RF timer reaches one minute.
8. Reset the RF timer to some value other than 1:00.
9. Initiate an RF cycle.
10. Ensure that RF delivery ceases when the RF timer reaches the new setpoint.
11. Reset the RF timer to 2:00 minutes.

Locale Configuration

To access the Locale Configuration screen, select Options (Figure 8).

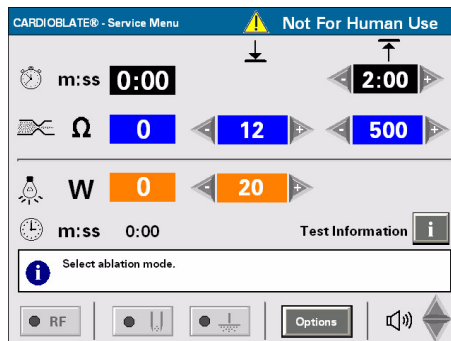


Figure 8. Options Menu

The Locale Configuration screen will appear (Figure 9).

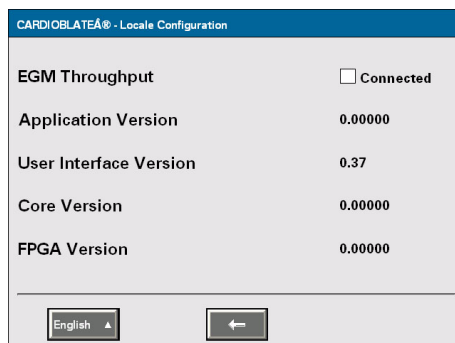


Figure 9. Locale Configuration

The Locale Configuration screen displays the following software information for the Diagnostic Application:

- Application Version
- User Interface Version
- Core Version
- FPGA Version

EGM Throughput

This allows the user to turn on or off the Electrogram (EGM) throughput during ablation. The EGM throughput sends information from the connections on the ablation device to EGM monitoring equipment.

Note: This feature is designed for future upgrades and is for reference only.

Changing the Language

1. Select the current language tab on lower left side of the Locale Configuration screen (Figure 10).
2. Select desired language.
3. Preferences will be saved upon exit.

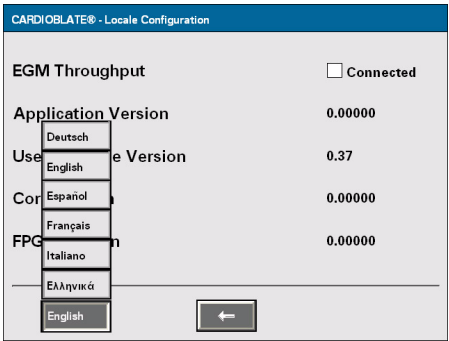


Figure 10. Changing the Language

End of Life Disposition

Do not dispose of this product in the unsorted municipal waste stream. Follow local regulations for proper disposal. Please refer to Medtronic web site <http://recycling.medtronic.com> for proper disposal guidance to ensure compliance with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive.

Medtronic Warranty Information

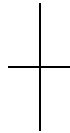
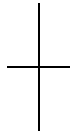
Limited Warranty for the Model 60889 Diagnostic Kit

- A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Medtronic® Cardioblate® Diagnostic Kit, hereafter referred to as the "Equipment," that should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any defective part or parts of the Equipment; (b) issue to the purchaser a credit equal to the original Equipment purchase price (but not to exceed the value of the replacement Equipment), against the purchase of replacement Equipment, or (c) provide functionally comparable replacement Equipment at no charge.
- B. To qualify for this repair, replacement or credit, the following conditions must be met:
- C. The Equipment must be returned to Medtronic within sixty (60) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).
- D. The Equipment must not have been repaired or altered by someone other than Medtronic in any way that, in the judgment of Medtronic, affects its stability and reliability.
- E. The Equipment must not have been subjected to misuse, abuse or accident.
- F. This LIMITED WARRANTY is limited to its express terms. IN PARTICULAR, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY USE, DEFECT OR FAILURE OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
- G. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

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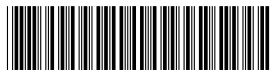
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